UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JOHN T. HESLIN as Administrator ad Prosequendum for the heirs-at-law of ERIN P. HESLIN, deceased and Administrator of the Estate of ERIN P. HESLIN, deceased, JOHN T. HESLIN, individually, **Plaintiffs,** **v.** **NEW JERSEY CVS PHARMACY, LLC and PERRIGO,** **Defendants.**	Civil Action No.: 2:21-cv-06698-WJM **OPINION**

WILLIAM J. MARTINI, U.S.D.J.:

This matter comes before the Court upon Defendant L. Perrigo Company's ("Perrigo[1]") Motion to Dismiss (the "Motion") Plaintiffs John T. Heslin, as administrator as prosequendum for the heirs-at-law of Erin P. Heslin and administrator of the Estate of Erin P. Heslin and John T. Heslin, individually, ("Plaintiffs") First Amended Complaint ("FAC") pursuant to Federal Rule of Civil Procedure 12(b)(6). ECF Nos. 31, 42. For the reasons set forth below, Perrigo's Motion is **GRANTED**.

I. BACKGROUND

The case arises from the death of Erin P. Heslin. Plaintiffs allege that between September 20, 2019 and June 3, 2020, Erin P. Heslin frequently purchased Perrigo's over the counter anti-diarrhea drug, loperamide[2], at New Jersey CVS Pharmacy LLC ("CVS" and with Perrigo, "Defendants"). *See* FAC at ¶ 41. Beginning after September 20, 2019, Erin Heslin would frequently purchase high volumes of loperamide. *Id.* at ¶ 16. Some of these packages contained over 200 mg of loperamide. *Id.* Erin Heslin died intestate on June 3, 2020, allegedly as a result of her consumption of loperamide. Plaintiffs allege Defendants disregarded and failed to comply with three Food and Drug Administration

[1] Per a January 11, 2023 stipulation, the parties agreed to have L. Perrigo Company substituted as a defendant and all allegations directed at Perrigo to be treated as directed at L. Perrigo Company. ECF Nos. 39, 40.

[2] The Court takes judicial notice that Perrigo's loperamide is a generic drug marketed under an abbreviated new drug application ("ANDA"). *See* Def. Mot., Exs. D-H; *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997); *In re Donald J. Trump Casino Sec. Litig.*, 7 F.3d, 357, 368 n.9 (3d Cir. 1993) ("[A] court may consider an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document.") (Internal quotations omitted).

("FDA") safety announcements. The first, on June 7, 2016, provided a "warning about serious heart problems with high doses of the antidiarrheal medicine loperamide including from abuse and misuse." *Id.* at ¶ 8. The second, on January 30, 2018, provided that the maximum approved safe use of loperamide, sold under the brand name Imodium A-d, was 8 mg per day for adults and 16 mg per day for prescription use. *Id.* at ¶ 9. The third, on September 20, 2019, "limited each carton of loperamide to no more than 48 mg." *Id.* at ¶ 10.

Plaintiffs filed their complaint on February 22, 2021 in the Superior Court of New Jersey, Law Division, Middlesex County and subsequently removed their action to this Court on March 25, 2021 on the basis of diversity subject matter jurisdiction pursuant to 28 U.S.C. § 1441(b) and 28 U.S.C. § 1332. ECF No. 1. The original complaint only included claims against CVS. Plaintiffs amended their complaint on November 23, 2022 to include claims against Perrigo as well. ECF No. 31. The FAC contains three counts. Count One, pursuant to New Jersey's Wrongful Death Act ("NJWDA"), N.J.S.A. 2A:31-1, and New Jersey's Survival Act ("NJSA"), N.J.S.A. 2A:15-3, alleges CVS failed to restrict the sale of loperamide once they were on alert "that the loperamide they were selling to invitee/patients was sometimes being abused." FAC at ¶ 24. Count One further alleges CVS was aware or should have been aware of Erin Heslin's quantity and volume of loperamide purchases from the frequency of her visits and through her use of CVS's Extracare card accounts. *Id.* at ¶¶ 17, 18. Lastly, Count One also alleges CVS failed to comply with the FDA's three announcements regarding loperamide. *Id.* at ¶ 14. Count Two, pursuant to the NJWDA and NJSA, alleges that Perrigo, as a manufacturer of loperamide, was negligent. *Id.* at ¶¶ 33-57. Specifically, Perrigo allegedly failed to comply with state and federal drug laws, including the FDA announcements, sold its product in excess of the FDA's limit, and knew or should have known the danger of serious heart problems associated with loperamide. Count Two alleges Perrigo was negligent in their actions regarding the manufacturing of loperamide and was aware or should have been aware of Erin Heslin's excessive purchases of the drug. Finally, Count Three, also under the NJWDA and NJSA, reiterates the above allegations as to Perrigo, but additionally charges them with "willful and wanton disregard for their invitees and customers." *Id.* at ¶ 61. Defendant Perrigo filed its Motion to Dismiss Counts Two and Three on January 20, 2023. ECF No. 42. Plaintiffs filed their opposition on February 7, 2023, and Perrigo filed its reply on February 14, 2023. ECF Nos. 47, 49.

II. LEGAL STANDARD

Rule 12(b)(6) of the Federal Rules of Civil Procedure ("FRCP") provides for the dismissal of a complaint if the plaintiff fails to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). The movant bears the burden of showing that no claim has been stated. *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005). In deciding a motion to dismiss under FRCP 12(b)(6), "all allegations in the complaint must be accepted as true, and the plaintiff must be given the benefit of every favorable inference to be drawn therefrom." *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011). The Court need not accept as true "legal conclusions," and "[t]hreadbare recitals of the elements of a cause of

action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In ruling on a 12(b)(6) motion, the Court is ordinarily limited to the facts as alleged in the complaint, the exhibits attached thereto, and matters of public record. *Pension Benefit Guar. Corp. v. White Consol. Indus.*, 998 F.2d 1192, 1996 (3d Cir. 1993). The Court may, however, look outside the pleadings and also consider "document[s] integral to or explicitly relied upon in the complaint" or any "undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document." *In re Asbestos Prod. Liability Litig. (No. VI)*, 822 F.3d 125, 134 n.7 (3d Cir. 2016).

To survive a 12(b)(6) motion, "a complaint must contain sufficient factual matter . . . to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.*

III. DISCUSSION

Defendant Perrigo moves to dismiss Counts Two and Three on preemption grounds and, alternatively, argues Plaintiffs' claims must be pled as a single cause of action under the New Jersey Products Liability Act ("NJPLA"). Perrigo contends that Plaintiffs' allegations that Perrigo "failed to restrict the sale of loperamide, breached an alleged duty 'to make safe the sale of loperamide,' breached an alleged duty to ensure the safety of its product,' and breached alleged duties to 'be in compliance with state and federal drug laws,'" essentially amount to claims that Perrigo should have simply stopped selling the drug. Def. Mot. at 17-18, ECF No. 42. Perrigo argues that loperamide, as a generic drug, is regulated by the Food, Drug, & Cosmetic Act, 21 U.S.C. §§ 301-397 ("FDCA") and therefore Plaintiffs' claims are preempted. Furthermore, any claims regarding Perrigo's failure to comply with the FDA announcements are "failure to warn allegations in substance and are preempted by federal law." Def. Mot. at 18. Plaintiffs argue the FDCA does not preempt their state law claims because common law claims do not provide an obstacle to the accomplishment of Congressional purposes in the FDCA. Pl. Opp. at 4. Plaintiffs further argue that their claims do not amount to "stop-selling" claims, but rather to "modify the selling of loperamide" pursuant to the FDA announcements, which modified carton limits to no more than 48 mg. *Id.*at 7. The Court agrees with Perrigo that Counts One and Two are preempted by federal law.[3]

[3] Count Three of Plaintiff's FAC also contains allegations that Perrigo breached its duty to make safe the sale of loperamide "[w]ith willful and wanton disregard for their invitees and customers." However, as the FAC makes clear, Perrigo is a manufacturer of loperamide and has, for the purposes of this case, sold its product to CVS Pharmacy and not to consumers directly. Furthermore, Plaintiff has not alleged any facts that, if true, support a plausible claim that Perrigo acted willfully, wantonly, or recklessly.

"The doctrine of preemption has constitutional roots in the Supremacy Clause," which provides that federal law is "supreme." *Sikkelee v. Precision Airmotive Corp.*, 907 F.3d 701, 709 (3d Cir. 2018) (quoting U.S. Const. art. VI, cl. 2). Generally, federal preemption arises under three circumstances: "(1) when a federal statute includes 'an express provision for preemption'; (2) '[w]hen Congress intends federal law to "occupy the field"' in an area of law; and (3) when a state and federal statute are in conflict." *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig. (No. II)* 751 F.3d 150, 158-59 (3d Cir. 2014). Although there is a presumption against preemption in areas traditionally within the states' police powers, such as healthy and safety, "certain state-law claims against manufacturers of generic drugs conflict directly with federal law and are without effect because of impossibility preemption." *In re Fosamax*, 751 F.3d 150,160. State law failure-to-warn claims against generic drug manufacturers are preempted by the FDCA because generic drug manufacturers have a "federal-law duty to keep [their] label the same" as the brand-name's. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011); accord *In re Fosamax,* 751 F.3d at 162-163. The FDCA also "preempts any state-law claim that exists 'solely by virtue' of an FDCA infraction." *Plourde v. Sorin Grp. USA, Inc.*, 23 F.4th 29, 33 (1st Cir. 2022) (quoting *Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 353, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001)). Put differently, if a violation of an FDCA requirement is the basis for a state law claim, then the state law claim is preempted. *See id.* Thus, where "the existence of the [ ] federal enactments [is] a critical element in the[ ] case," such a claim is preempted because such litigation "would exert an extraneous pull on the [regulatory] scheme established by Congress." *Buckman*, 531 U.S. at 353.

Courts must, therefore, analyze "whether there is an underlying state tort duty and make the preemption decision based on the existence or absence of this duty." *Polt v. Sandoz, Inc.*, 462 F. Supp. 3d 557, 565 (ED. Pa, 2020). "Except in circumstances not relevant here, 'all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.'" *McDaniel v. Upsher-Smith Labs.. Inc.*, 893 F.3d 941, 944 (6th Cir. 2018) (quoting 21 U.S.C. § 337(a)). "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance. . ." *Buckman*, 531 U.S. at 349 n.4. "[T]he FDCA does not provide a private right of action for a defendant's violation of its provisions." *Frei v. Taro Pharms. U.S.A.*, 443 F. Supp. 3d 456, 468 (S.D.N.Y, 2020) (citing *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 810 (1986)).

In similar cases against brand-name drug manufacturers regarding harmful side effects from the consumption of its generic counterpart, some courts have considered a theory known as "innovator liability" or "warning label liability." *See Jenny Ange, Am I My Competitor's Keeper? Innovator Liability in the Fifty States*, 21 Colum. Sci. & Tech. L. Rev. 1, 4 (2019). Innovator liability "recognizes that—by operation of federal law—the brand-name company has near-exclusive control of the design and warning labels that generic companies must use for bio-equivalent generic drugs [and. . .] that federal law preempts state law claims against generic companies for design defects and failing to warn

about the risks of a bio-equivalent generic drug." *Doran v. Glaxosmithkline PLC*, 607 F. Supp. 3d 192, 197 (D. Conn. 2022).

Here, both Counts Two and Three[4] against Perrigo, a generic manufacturer, amount to "failure to warn" claims, FDCA violations, and "failure to restrict sale" claims. Since a generic manufacturer must use the same label as the brand-name manufacturer, it would be impossible for Perrigo to change its loperamide label to comply with state law. The FDA's duty of sameness preempts any state law duty that would require a generic drug manufacturer to change its label. *See Roncal v. Aurobindo Pharma USA, Inc., No. 3:20-cv-02643*, 2022 U.S. Dist. LEXIS 76429, at *12 (D.N.J. Apr. 27, 2022). The duty of sameness would extend to Perrigo's inability to change the maximum approved daily dose (Def. Mot. Ex. B), limiting each carton (*Id.*), and providing a warning about serious heart problems with high doses (*Id.* at Ex. A). Under the Hatch-Waxman Act, generic drugs must have the same "dosage form," "strength," and "labeling" as the name brand versions. *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 477 (2013); 21 U. S. C. §§355(j)(2)(A). Furthermore, generic manufacturers are prohibited from making any unilateral changes to a drug's label – precisely what Plaintiff suggests Perrigo could have or should have done in this case. Plaintiff's allegations also indicate that Perrigo failed to comply with the 2016, 2018, and 2019 FDA safety announcements regarding loperamide. Failure to comply with these safety announcements may amount to FDCA violations, but nonetheless any said violations would only be enforceable with the Federal Government filing suit, not private litigants. *See Frei*, 443 F. Supp. 3d at 468. Therefore, Defendant Perrigo's motion to dismiss Counts Two and Three is **GRANTED**. Counts Two and Three are **DISMISSED WITH PREJUDICE**.

IV. CONCLUSION

For the reasons set forth above, Defendant's Motion is **GRANTED**. Counts Two and Three are **DISMISSED WITH PREJUDICE**.

An appropriate order follows.

WILLIAM J. MARTINI, U.S.D.J.

Date: May 4, 2023

[4] Counts Two and Three contain allegations that Perrigo was aware or should have been aware or Erin Heslin's quantity and volume of loperamide purchases. FAC at ¶¶ 49, 62. However, given that Perrigo is the manufacturer of loperamide and the FAC only alleges Perrigo sold its product to CVS Pharmacy, not Erin Heslin, these allegations fall short despite also being preempted.